REMARKS

This is in response to the Office Action mailed on October 2, 2008 in which claims 1-5 were rejected. With this Amendment, claims 1, 2, and 3 are amended. All amendments are fully supported by the original specification and drawings. No new matter is added. Claims 1-5 are pending in this application. In light of the foregoing amendments and following remarks, Applicant respectfully requests advancement of this application to allowance.

Claim Rejections – 35 U.S.C. § 101

In the Office Action, claims 1-5 were rejected under 35 U.S.C. § 101 as being directed to non-statutory subject matter. The rejection relies upon the USPTO's interim guidelines for examination of patent applications for patent subject matter eligibility dated October 26, 2005. Specifically, the Office Action relies upon the useful, tangible, and concrete results test articulated in those guidelines. Applicant respectfully traverses this rejection.

On October 30, 2008 (shortly after the Office Action issued), the Federal Circuit decided *In re Bilski* which deals with the patentability of method claims under 35 U.S.C. § 101. *In re Bilski* overruled the useful, concrete, and tangible result test, ("that inquiry is insufficient to determine whether a claim is patent eligible under § 101" and "we also conclude that the 'useful, concrete and tangible result' inquiry is inadequate") and clarified that the proper test is the machine-or-transformation test ("we . . . reaffirm that the machine-or-transformation test outlined by the Supreme Court is the proper test to apply"). Slip op. at page 20.

In re Bilski describes the machine or transformation test as follows: "A claimed process is surely patent-eligible under § 101 if: (1) it is tied to a particular machine or apparatus, (2) it transforms a particular article into a different state or thing." The court also stated, "the machine-or-transformation test is a two-branched inquiry: An Applicant may show that a process claim satisfies § 101 either by showing that its claim is tied to a particular machine, or by showing that its claim transforms an article." In re Bilski also set forth a number of exceptions. First, (the use of a specific machine or transformation of an article must impose meaningful

limits on the claim's scope to impart patent-eligibility." Second, "the involvement of the machine or transformation in the claimed process must not merely be insignificant extra solution activity."

Claims 1-5 satisfy the machine or-transformation test because the claims are tied to a particular machine. For example, the preamble of claim 1 recites "a method of monitoring the operation of a prosthetic assist device." The prosthetic assist device is a machine. Claim 1 further recites, "attaching a non-invasive sensor externally to a patient." A non-invasive sensor is also a machine. Claim 1 further recites "separately monitoring, utilising said sensor, the blood flow. . ." Therefore, claim 1 includes a machine that imposes meaningful limits on the claim's scope (e.g., a machine is positively recited as performing multiple elements of the method) and is not merely insignificant extra solution activity. Claims 2-5 depend from claim 1. Therefore, claims 1-5 satisfy the machine-or-transformation test and are therefore patentable under 35 U.S.C. § 101. Reconsideration and allowance of claims 1-5 is respectfully requested.

Claim Rejections – 35 U.S.C. § 102

In the Office Action, claims 1-5 are rejected under 35 U.S.C. § 102(e) as being anticipated by Landesberg (U.S. Patent No. 6,511,413). Applicant respectfully traverses the rejection because Landesberg fails to disclose each element of claim 1. However, in an effort to advance this application to allowance, claim 1 is amended.

Claim 1 is directed to a method of monitoring the operation of a prosthetic assist device. The method includes "(a) attaching a non-invasive sensor externally to a patient to monitor directly the blood flow through at least one heart ventricle to obtain a first measurement; (b) separately monitoring, utilising said sensor, the blood flow through the prosthetic assist device to obtain a second measurement; and (c) combining said two measurements to determine an overall native to prosthetic flow index so as to determine the effectiveness of the operation of said prosthetic assist device."

A. Landesberg does not disclose a non-invasive device

Landesberg is a ventricular-assist device (see title and Abstract) having built-in monitoring functions. The ventricular-assist device is not a non-invasive device. For example, Landesberg describes two monitoring transducers, where "one is inserted into the LV cavity and the second is placed in the aortic arch." Col. 19, lines 1-3. "The transducers can be inserted percutaneously through major arteries but a pressure gauge on the ventricular edge of the annula can be used instead." Col. 19, lines 3-5. See, also, FIG. 2 illustrating direct interaction with the heart (which can only be performed in an invasive manner).

Landesberg expressly states that the procedure is invasive: "During the studies the heart was exposed by mid-line sternotomy and pericardiotomy. Normally, however, the device is implanted by a small thoractomy that will expose the ventricle (apex), so that the annula will be introduced into the ventricle by a minimal invasive procedure." Col. 19, lines 6-10.

Both a sternotomy/pericardiotomy and the annula being introduced into the ventricle by a "minimal invasive procedure" are invasive procedures. In contrast, claim 1 recites "(a) attaching a non-invasive sensor externally to a patient to monitor directly the blood flow through at least one heart ventricle to obtain a first measurement" (emphasis added). Landesberg fails to disclose this element of claim 1.

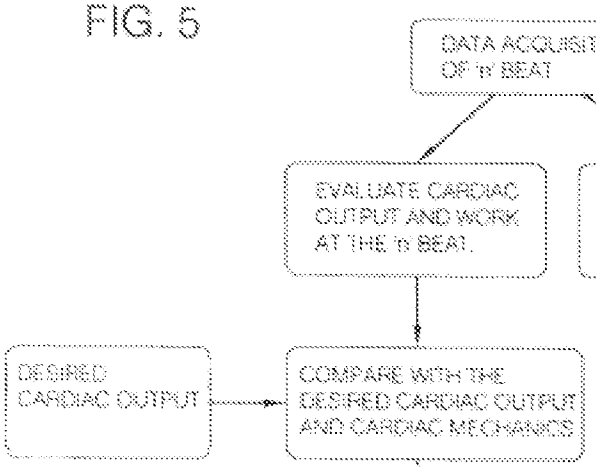
B. Landesberg does not disclose monitoring blood flow through a heart ventricle and separately monitoring blood flow through the prosthetic assist device to obtain the second measurement

Landesberg describes a system for assisting a failing ventricle using a ventricular assist device. The device operates to augment the cardiac output of the failing ventricle and increases the generated pressure. However, as discussed below, Landesberg fails to disclose monitoring directly the blood flow through at least one heart ventricle, but rather discloses monitoring the overall cardiac output.

Landesberg monitors an overall cardiac output that is the sum of the output of the failing heart and the output of the ventricular assist device. This is shown, for example, in FIGS. 5 and 6 of Landesberg, which illustrate the operation of the Landesberg system. A portion of FIG. 5 of

Landesberg is copied below for the Examiner's convenience (FIG. 6 also includes the same blocks).

FIG. 5



At the far left side of Figures 5 and 6 is a box labeled "Desired Cardiac Ouput". The desired cardiac output flows to another block labeled "Compare with the Desired Cardiac Output and Cardiac Mechanics." Another block also feeds into the "Compare with . . ." block, which is labeled "Evaluate Cardiac Output and work at the 'n' Beat." This shows that the system monitors the "cardiac output" and compares this with the "desired cardiac output." Cardiac output is defined in Landesberg as "the sum of the inflow through the cannula and the ventricle wall shortening." Therefore, Landesberg determines the total cardiac output including both the flow from the failing heart and also the inflow from the ventricle assist device.

In contrast, claim 1 recites "(a) attaching a non-invasive sensor externally to a patient to monitor directly the blood flow through at least one heart ventricle to obtain a first measurement" and "(b) separately monitoring, utilising said sensor, the blood flow through the prosthetic assist device to obtain a second measurement." Landesberg does not disclose monitoring the blood flow through the heart ventricle and separately monitoring blood flow through the prosthetic assist device.

C. Landesberg does not disclose determining an overall prosthetic flow index

As discussed above, Landesberg does not disclose monitoring directly the blood flow through at least one heart ventricle to obtain a first measurement, and also does not disclose separately monitoring, utilising said sensor, the blood flow through the prosthetic assist device to obtain a second measurement, as recited in claim 1. Since Landesberg does not disclose obtaining the first and second measurements, Landesberg also does not disclose subsequently combining the first and second measurements. Accordingly, Landesberg does not disclose "combining said two measurements to determine an overall native two prosthetic flow index," as recited in claim 1.

D. Landesberg does not disclose continuous wave Doppler flow monitoring (claim 2)

In addition to the differences between Landesberg and claim 1 noted above, claim 2 further recites "wherein said non-invasive device monitoring comprises continuous wave Doppler flow monitoring of the heart."

Landesberg fails to disclose this element of claim 2. Although Landesberg describes "a Doppler or an ultrasonic or electromagnetic flow meter measuring ventricle outlet flow" (column 8, lines 9-10), there are various types of Doppler that can be used. Landesberg does not disclose the use of continuous wave Doppler.

The Landesberg device is powered by an implanted battery (column 9, line 58). A common type of Doppler is pulse mode Doppler. Pulse mode Doppler requires less power than continuous wave Doppler. For this reason a device powered by an implanted battery, such as the Landesberg device, would be designed by a person of skill in the art to use pulse mode Doppler in order to conserve energy from the implanted battery.

The present application describes a device that utilises non-invasive techniques. As a result, continuous wave Doppler may be used instead of pulse mode Doppler. Landesberg fails to disclose this recited element. Reconsideration and allowance of claim 2 are respectfully requested.

E. Conclusion – 35 U.S.C. § 102

Landesberg fails to disclose multiple elements of claims 1 and 2. For these reasons, the rejection of claims 1 and 2 under 35 U.S.C. §102 should be withdrawn. Reconsideration and the allowance of claim 1, as well as claims 2-5 that depend therefrom, are respectfully requested. Applicant does not otherwise concede the correctness of this rejection.

CONCLUSION

In view of the foregoing amendments and remarks, Applicant respectfully requests a Notice of Allowance. There may be additional reasons that the pending subject matter is patentably distinct from the cited references in addition to those discussed herein. Applicant reserves the right to raise any such arguments in the future. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

MERCHANT & GOULD P.C.
P.O. Box 2903
Minneapolis, Minnesota 55402-0903
(612) 332-5300

Date: February 2, 2009

/Benjamin A. Tramm/
Benjamin A. Tramm
Reg. No. 62,303
BAT:ae

23552
PATENT TRADEMARK OFFICE